

| Practitioner's | Docket No. | 3342DL |
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|                |            |        |

**PATENT** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Rodney J.Y. Ho et al.

**Application No.: 10/757,775** 

**Group No.: 1617** 

Filed: January 14, 2004

Examiner: RAMACHANDRAN, Umamaheswari

For: LIPID-DRUG FORMULTIONS AND METHODS FOR TARGETED DELIVERY

OF LIPID-DRUB COMPLEXES TO LYMPHOID TISSUES

Commissioner for Patents Washington, DC. 20231

# DECLARATION OF PRIOR INVENTION IN THE UNITED STATES OR IN A NAFTA OR WTO MEMBER COUNTRY TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)

#### PURPOSE OF DECLARATION

| 1. This declaration is to establish completi  | on of the invention in this application in the                      |
|---|---|
| United States, at a date prior to200  | 2 that is the effective date  |
| of the prior art:   | •   |
| X publication   | ·   |
| patent  |   |
| that was cited by the   |   |
| X examiner.   |   |
| applicant.  |   |
| CERTIFICATE OF MAILING/TRANS I hereby certify that this correspondence is, on the date of |   |
| MAILING   | FACSIMILE   |
| deposited with the United States Postal Service with sufficient postage as first class    | transmitted by facsimile to the Patent and Trademark Office         |
| mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.    | Jane Durger gabin   |
| Date 1 25-09  | Signature  206.621.14 33  (type or print name of person certifying) |

(Declaration of Prior Invention In the United States or in a NAFTA or WTO Member Country to Overcome

Cited Patent or Publication—37 C.F.R. § 1.131 [g-32] - page 1 of 3)

NOTE: "When any claim of application or a patent under reexamination is rejected under 35 U.S.C. 102(a) or (e), or 35 U.S.C. 103 based on a U.S patent to another or others which Is pier art wider 35 U.S.C. 102(a) or (e) and which substantially shows ot describes but does not claim the same patentable invention, as defined in 37 C.F.R 1.601(n), or a reference to a foreign patent or to a printed publication, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43 or 1.47, may substitute an appropriate oath or declaration to overcome the patent or publication. The oath or declaration must include facts showing a completion of the application in this country or in a NAFTA or WTO member country before the fling date of the application on which the U.S. patent issued, or before the date of the foreign patent, or before the date of the printed publication. When an appropriate oath or declaration is made, the patent or publication cited shall not bar the grant of a patent to the inventor or the confirmation of the patentability of the claims of the patent, unless the date of such patent or printed publication is more than one year prior to the date on which the inventor's or patent owner's application was filed in this country." 37 C.F.R. § 1.131(a)(1).

NOTE:37 C.F.R § 1.131 Is not applicable to a rejection based on a U.S. patent that CLAIMS the rejected invention.

| 2. | The | person | making | this | dec | larat | ion | is ( | (are) | ): |
|----|-----|--------|--------|------|-----|-------|-----|------|-------|----|
|----|-----|--------|--------|------|-----|-------|-----|------|-------|----|

- X\_the Inventor(s).
- \_ only some of the joint inventor(s)
- (and a suitable excuse is attached for failure of the omitted joint inventor(s) to sign)
- the party in interest
- (and a suitable explanation as why it is not possible to produce the declaration of the inventor(s) is attached)

#### FACTS AND DOCUMENTARY EVIDENCE

3.

NOTE: The showing of facts shall be such, in character and weight as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. 37 C.F.R. § 1.131(b).

To establish the date of completion of the invention of this application, the following attached documents and/or models are submitted as evidence:

(check all applicable items below)

- X invention disclosure and disclosure document
- $\overline{X}$  correspondence
- photographs
- X reproduction(s) of notebook entries
- supporting statement(s) by witness(es) (where verbal disclosures are the evidence, relied upon)

NOTE: While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See Margenthaler v. Scudder 1897C.D. 724,81 O.G.1417. "See also M,P.EP. § 715.07 and § 2138.04, 7th ed.

From these documents and/or models, it can be seen that the invention in this application was made

X at least by the date of 6/30/1999 which is a date earlier than the effective date of the reference and was fully disclosed prior to March 22, 2000.

NOTE: "If the dates of the exhibits have been removed or blocked off, the matter of dates can be taken care of in the body of the oath or declaration." M.P.EP § 715.07, 7th ed.

NOTE: "[T]he dates in the oath or declaration may be the actual dates, or, if the applicant or patent owner does not desire to disclose his or her actual dates,, he or she may merely allege that the acts referred to occurred prior to a specified date." M.P.E. P. § 715.07, 7th ed

#### DILIGENCE

- NOTE: "Where there has not been reduction to practice prior to the date of the reference, the applicant or patent owner must also show diligence in the completion of his or her invention from a time just prior to the date of the reference continuously up to the date of the actual reduction to practice or up to the date of filing his or her application (filing constitutes a constructive reduction to practice, § 1.131). "M.P.E.P. § 715.07, 6th ed., rev. 3 (emphasis added).
- NOTE: "A conception of an invention, though evidenced by disclosure, drawings, and even a model, is not a complete invention under the patent laws, and confers no rights on a inventor, and has no effect on a subsequently granted patent to another, UNLESS HE OR SHE FOLLOWS ITWITH REASONABLE DILIGENCE BY SOME OTHER ACT, such as an actual reduction to practice or filing an application for a patent. Automatic Weighing Mach. Co v. Pneumatic Scale Corp., Limited 1909 C.D. 498, 139 O.G. 991, M.P.E.P. §715.07, 7th ed.
  "Conception in the mental part of the inventive act, but it must be capable of proof, as by drawings, complete disclosure to another person, etc., In Mergenthaler v. Scudder, 1897 ca 724,81 O.G. 1417, it was established that conception is more than a mere vague idea of how to solve a problem; the means

NOTE: Only diligence before reduction to practice is a material consideration. The "lapse of time between the completion or reduction to practice of an invention and the filing of an application thereon." (Ex parte Merz 74 U.S.P.Q. 296) is not relevant to an affidavit or declaration under 37 C.F. R. § 1.131. M.P.E.P. § 715.07(a), 7th ed.

themselves and their interaction must be comprehended also." M.P.E.P. § 715.07, 7th ed.

Attached is a statement establishing the diligence of the applicants, from the time of their conception, to a time just prior to the date of the reference, up to the:

X actual reduction to practice. filing of this application.

### TIME OF PRESENTATION OF THE DECLARATION

(complete (a), (b) or (c))

- (a) X This declaration is submitted prior to final rejection.
- (b) \_\_ This declaration is submitted with the first response after final rejection, and is for the purpose of overcoming a new ground of rejection or requirement made in the final rejection.
- (c) \_\_ This declaration is submitted after final rejection. A showing under 37 C.F.R. § 1.116(b) is submitted herewith.

(Declaration of Prior Invention In the United Stales or In a NAFTA or WTO Member Country to Overcome Cited Patent r Publication—37 C.F.R, § 1.131 [9-32]—page 3 of 3)

# DECLARATION

6. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on Information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

| 7. (complete A or B below)                                |
|---|
| A. Inventor(s)  |
| Full name of sole or first inventorRodney-1507110         |
| Inventor's signature                                      |
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|   |
| Full name of second joint inventor, if any Che-Chung Tsai |
| Inventor's signature Chelling 15                          |
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|   |
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| Inventor's signature                                      |
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| Residence   |
| Post Office Address                                       |
| ·   |